

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 523.1006US
INTERNATIONAL APPLICATION NO. PCT/US2004/019816		U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.53) 104560889
INTERNATIONAL FILING DATE 21 June 2004		PRIORITY DATE CLAIMED 20 June 2003; 20 June 2003; October 21, 2003
TITLE OF INVENTION TOPICAL THERAPY FOR THE TREATMENT OF MIGRANES, MUSCLE SPRAINS, MUSCLE SPASMS, SPASTICITY AND RELATED CONDITIONS		
APPLICANT(S) FOR DO/EO/US RONALD AUNG-DIN		

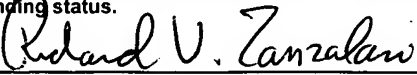
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Datasheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Unexecuted Declaration/Power of Attorney; Express Mail Label EV 717 227 612US

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

U.S. APPLICATION NO. 10/560889 To be assigned		INTERNATIONAL APPLICATION NO. PCT/US2004/019816		ATTORNEY'S DOCKET NO. 523.1006US	
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21.	<input checked="" type="checkbox"/>	Basic national fee.....	\$300	\$ 300.00	
22.	<input checked="" type="checkbox"/>	Examination fee			
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 333(1)-(4)				\$ 200.00	
All other situations.....				\$200	
23.	<input checked="" type="checkbox"/>	Search fee			
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority				\$ 400.00	
International Search Report prepared and provided to the Office				\$400	
All other situations.....				\$500	
TOTAL OF 21, 22 and 23 =				\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		RATE	
- 100 =	/50 =			x \$250 =	\$
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	44 - 20 =	14	x \$50 =	\$ 700.00	
Independent Claims	3 - 3 =	0	x \$200 =	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360 +	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 1600.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 C.F.R. 1.27. Fees above are reduced by 1/2.				\$ 800.00	
SUBTOTAL =				\$ 800.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 800.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$800.00 to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0552 . A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Davidson, Davidson & Kappel, LLC 485 Seventh Avenue, 14th Floor New York, NY 10018 (212)-736-1940			 SIGNATURE Richard V. Zanzalari NAME 49,032 REGISTRATION NUMBER		
Dated: December 15, 2005					

10/560889

Certificate of Express Mailing under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 in an envelope addressed to:

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on December 15, 2005.

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Signature

Errick Smalls

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212-736-1940

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Telephone Number

EV 717 227 612 US

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Note: Each paper must have its own certificate of mailing by Express Mail, or this certificate must identify each submitted paper.

Re.: Docket No.: 523.1006US
Applicant(s): Ronald AUNG-DIN
Serial No.: To be Assigned
Invention: TOPICAL THERAPY FOR THE TREATMENT OF MIGRANES, MUSCLE SPRAINS,
MUSCLE SPASMS, SPASTICITY AND RELATED CONDITIONS
Filing Date: Herewith

Enclosed Are:

- Transmittal Letter (35 U.S.C. 371) (2 pages);
- Copy of International Appl. No. PCT/US2004/019816 as published (50 pages);
- Application Data Sheet (2 pages);
- Preliminary Amendment (10 pages);
- Unexecuted Declaration/Power of Attorney Form (1 page);
- Return Postcard; and
- Check in the amount of \$ 800.00

This collection of information is required by 37 CFR 1.10. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.